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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,641	05/03/2002	Dae Gun Kim	6181/OK439	3102

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EXAMINER	
WHITEMAN, BRIAN A	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,641	KIM ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *20* is/are allowed.

6)☒ Claim(s) *19 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Non-Final Rejection

Claims 11-21 are pending.

Applicants' traversal and the amendment to claims 19 and 20 in the paper filed on 1/11/06 is acknowledged and considered by the examiner.

Election/Restrictions

Claims 11-18 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/5/04.

Oath/Declaration

The oath or declaration remains defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: the method claims 19-21 were not filed in the original application with the original oath and there is no statement or indication in the file of record that all of the inventors listed in the original oath were the inventors of the newly added method claims.

It is noted that Applicants indicate that they will provide a new oath upon allowance of claimed subject matter. Thus, the oath remains defective.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 19 and 21, as best understood, are readable on a genus of wild type P972 genes, wherein the genus of genes is not claimed in a specific biochemical or molecular structure that could be envisioned by one skilled in the art at the time the invention was made are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The applicants disclose that the accession no. AF078078 in the instant specification is for GADD45gamma mRNA, also known as P972 (page 5). Applicants disclose production of wild type P972 cDNA (page 12). In the specification, the applicant contemplates the P972 gene of the present invention can include promoters, transcription response elements, enhancers, etc. See page 5. The specification does not provide a definition of the term gene. The definition of a gene in the art is unclear because it is not apparent if a gene only refers to the open reading frame or refers to exons/introns and the control regions of the gene. There is no evidence of record that

GADD45gamma mRNA had a known structural relationship to a genus of wild type P972 genes. Based upon the prior art and the difference between the accession no. AF078078 and a genus of P972 genes there is expected to be variation among species of genes. The specification does not describes P972 genes. In view of the above considerations one of skill in the art would not recognize that the specification sufficiently describes a genus of claimed genes because GADD45gamma mRNA is not a representative species of the claimed genus of claimed genes. It is apparent that on the basis of applicant's disclosure, an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to potential methods and/or molecular structures of molecules that are essential for the genus of genes as claimed; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of biochemical or molecular structures of genes that must exhibit the disclosed biological functions as contemplated by the claims.

Vas-Cath Inc. v Mahurkar, 935 F.2d, 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991), makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purpose of the 'written description' inquiry, *whatever is now claimed*." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath, See MPEP 2163).

With the exception of the Accession No. AF078078, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or the simplicity of the method of isolation. Adequate written description

requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. v Chugai Pharmaceutical Co. Ltd., 18 USPQ 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification only provided the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that, "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997): *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement 'by describing the invention, with all it claimed limitations, not that which make it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc. that set forth the claimed invention." *Lockwood*, 107F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmid and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Dir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. At 1170, 25 USPQ at 1606.
>
> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information, concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is not further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes; as the example does, does not necessarily describe the cDNA itself. No sequence information indication

> which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only the Accession No. AF078078, but not the full breadth of the claims (or none of the sequences encompassed by the claim) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed is not representative of the genus because the genus of wild type P972 genes is highly variant.

Claims 19 and 21 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using wild type P972 as disclosed in GenBank Accession No. AF078078 in the claimed invention, does not reasonably provide enablement for using a genus of wild-type P972 genes in the claimed method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

NOTE: If the claims are amended to recite GenBank Accession No. AF078078, a 112 second paragraph will be required. However, the nucleotide sequence (SEQ ID NO:) for Accession No. AF0787078, at the time the application was filed, could be incorporated into the specification and the claims to overcome the 112 first paragraph rejection and any future 112 first paragraph or second paragraph rejections. See 37 CFR 1.57.

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims read on using an expression vector comprising a genus of P972 gene to treat cancer in a mammal. Therefore, the claims are considered broad. The claims will therefore be

evaluated based upon using an expression vector comprising a P972 gene to treat cancer in a mammal.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation (United States v. Telectronics, Inc., 8 USPQ2d 1217 (Fed. Cir. 1988). Whether undue experimentation is required is not based upon a single factor, but rather a conclusion reached by many factors. These factors were outlined in Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in In Re Wands (see above).

With respect to the term "p972 gene" in the instant claims, the specification defines the term as "the P972 gene modified to express the protein expressed by the wild type P972 gene or other proteins that functionally equivalent to the same as well as the wild type P972 gene (GenBank Accession No. AF078078)." "The P972 gene of the present invention can include more than one factor that can lead to the expression of the P972 gene inside a cell." For example, the P972 gene of the present invention can include promoters, transcription response elements, enhancers, etc." See page 5. The instant specification also indicates that P972 is also referred to as Gadd45gamma, CR6, or OIG37 (abstract). Thus, the term is considered broad.

The accession no. AF078078 in the instant specification is for GADD45gamma mRNA and not for a GADD45gamma gene. The skilled artisan understands that sequences present in GenBank records can change from time to time and such changes are not defined by the disclosure or under control of the applicants. Furthermore, a search of the term in GenBank results in one hit for a Phytophthora alni subsp. (multiformis strain P972 internal transcribed spacer 1, partial sequence; 5.8S ribosomal RNA gene, complete sequence; and internal

transcribed spacer 2, partial sequence) with a different GenBank Accession No. AY689136). In view of the diverse sequences that are embraced by the term, the skilled artisan could not use the genus of P972 genes in the claimed method without performing undue experimentation for determining which sequences are considered wild type P972 genes in treating cancer cells lacking P972 expression.

The court in Enzo 188 F.3d at 1374, 52 USPQ2d at 1138 states:

> It is well settled that patent applications are not required to disclose every species encompassed by their claims, even in an unpredictable art. However, there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed.
> In re Vaeck, 947 F.2d 48, 496 & n.23. 30 USPQ2d 1438, 1445 &n23 (Fed. Cir. 1991)(citation omitted). Here, however, the teachings set forth in the specification provide no more than a "plan" or "invitation" for those of skill in the art to experiment...; they do not provide sufficient guidance or specificity as to how to execute that plan. See Fiers v. Revel. 984 F.2d.1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993); In re Wright, 999 F.2d...[1557], 1562, 27 USPQ2d...[1510], 1514. [Footnote omitted].

On this record, it is apparent that the instant specification provides no more than a plan or invitation in view of the art of record exemplifying the unpredictability of using a genus of P972 genes in the cancer gene therapy, for those skilled in the art to further experiment with a genus of sequences so as to provide a sufficient number of sequences that could be used in the claimed method of gene therapy as intended by the instant specification at the time the invention was made.

See also Genentech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42, USPQ2d 1001, 1005 (Fed. Cir. 1997)

> ("Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable the public to understand and carry out the invention.")

In view of the art of record and the lack of guidance provided by the specification; the specification does not provide reasonable detail for what sequences are considered wild type P972 genes, and it would take one skilled in the art an undue amount of experimentation to reasonably extrapolate from the assertion in the specification to practicing the claimed invention. Therefore, the instant specification is not enabled for the claimed invention.

Given the above analysis of the factors, it is concluded that the instant specification and the claims coupled with the art of record, at the time the invention was made, the specification does not provide sufficient guidance and/or evidence to reasonable enable the claimed invention. Given that cancer gene therapy wherein an expression vector (adenovirus) is employed to treat a genus of tumors in a mammal was unpredictable at the time the invention was made, and given the lack of sufficient guidance as to using a genus of P972 genes in a cancer gene therapy as cited in the claims, one skilled in the art would have to engage in a large quantity of undue experimentation in order to practice the claimed invention based on the applicants' disclosure and the unpredictability of cancer gene therapy

Applicant's arguments filed 1/11/06 have been fully considered but they are not persuasive.

In response to applicant's argument that amending the claim to recite "wild type" P972 should overcome the rejection of record, the argument is not found persuasive because the term "wild type P972 gene" is still broad and reads on a genus of P972 genes that are not supported by teaching in the specification.

Response to Arguments

Applicant's arguments, see pages 4-5, filed 1/11/06, with respect to enablement rejection have been fully considered and are partially persuasive. The rejection of claims 19-21 with respect to using a genus of administration routes and cells in the claimed invention has been withdrawn because of the amendment to claims 19 and 20.

Applicant's arguments, see page 6, filed 1/11/06, with respect to enablement rejection have been fully considered and are persuasive. The rejection of claim 20 with respect to deposit requirement is withdrawn because applicants has meet the requirements of 37 CFR 1.804(a) and MPEP 2406.01.

Conclusion

Claim 20 is in condition for allowance because the claim is free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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